2018 Current Fiscal Year Report: Allergenic Products Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Allergenic Products Advisory Committee	784

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/09/2018	07/09/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$12,031.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$254,667.00	$233,193.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$15,312.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$63,667.00	$58,298.00
18d. Total	$318,334.00	$318,834.00
19. Federal Staff Support Years (FTE)	1.50	1.30

20a. How does the Committee accomplish its purpose?
The Committee reviews and evaluates data relating to the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human diseases in order to make appropriate recommendations to the Commissioner of Food and Drugs of its findings. It is anticipated that the Committee will meet once in FY 2019 to review data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products.

20b. How does the Committee balance its membership?
Members are selected from academic and clinical practice settings and include authorities in the areas of allergy, immunology, pediatrics, internal medicine, and biochemistry. One member is technically qualified and identified with consumer interests. The Committee may also include one non-voting member to represent industry's interests.

20c. How frequent and relevant are the Committee Meetings?
In FY 2018, the Committee did not meet. Per the charter this Committee is approved to meet approximately two times a year. It is anticipated that the Committee will meet once in FY 2019.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the Committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensations.

20e. Why is it necessary to close and/or partially closed committee meetings?
When needed, closed-sessions occur to permit discussion of trade secrets and/or commercial or financial information obtained from a person and privileged or confidential 552b(c)(4), or information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy 552b(c)(6).

21. Remarks
Although this committee did not meet in FY 2018, considerable time was devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website;

updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required.

Designated Federal Officer

Serina Amy Hunter-Thomas DFO

Committee Members	Start	End	Occupation	Member Designation
Assa'ad, Amal	03/23/2016	08/31/2019	Prof. of Clinical Pediatrics, Allergy and Immunology	Special Government Employee (SGE) Member
Finegold, Ira	09/01/2014	08/31/2018	Chief, Division of Allergy, St. Luke's-Roosevelt Hospital Center	Special Government Employee (SGE) Member
Keet, Corrine	09/14/2018	08/31/2022	Associate Professor of Pediatrics, Johns Hopkins School of Medicine	Special Government Employee (SGE) Member
Kelso, John	09/01/2013	02/08/2018	Clinical Professor of Pediatrics & Internal Medicine, Scripps Clinic	Special Government Employee (SGE) Member
Maleki, Soheila	09/14/2018	08/31/2022	Lead Scientist, U.S. Department of Agriculture	Regular Government Employee (RGE) Member
Peden, David	09/01/2014	08/31/2018	Professor of Pediatrics, University of North Carolina School of Medicine	Special Government Employee (SGE) Member
Peebles, Ray	11/17/2016	08/31/2020	Professor of Medicine	Special Government Employee (SGE) Member
Plunkett, Greg	01/01/2016	08/31/2019	Industry Representative	Representative Member
Portnoy, Jay	02/07/2017	08/31/2020	Consumer Representative	Special Government Employee (SGE) Member
Stone, Kelly	11/17/2016	08/31/2020	Deputy Chief and Senior Clinician	Regular Government Employee (RGE) Member

Number of Committee Members Listed: 10

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tabacco regulation, prevention, and control program; and management for organizational excellence and accountability. The Allergenic Products Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating available data relating to the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention or treatment of allergies and allergic disease. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based risk management in all of its

activities. The Committee recommendations provide the most health promotion and protection at the least cost for the public. This Committee assists the Agency in ensuring timely, high quality, cost-effective processes for review of new technologies/pre-market submissions, effective communication and working relationships with stakeholders to enhance U.S. and global health outcomes, accurately analyzing risks associated with medical products, facilitating the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian and military populations, protecting the safety and security of biologics are all key components of FDA's strategic plan objectives.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Allergenic Products Advisory Committee enables the Agency to

obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
19

Number of Recommendations Comments
The Committee made 19 recommendations from FY2003 through FY2018.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
79%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
5%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
The Agency usually does. Product approval issues are first released to the sponsor.

When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	✓
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

NA